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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/580,819	05/26/2000	Vadim Vladimirovich Yuzhakov	7606R	9337

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EXAMINER

DESANTO, MATTHEW F

ART UNIT PAPER NUMBER

3763

DATE MAILED: 04/22/2004

20

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/580,819

Applicant(s)

YUZHAKOV ET AL.

Examiner

Matthew F DeSanto

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 24 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 8-12, 20-24 and 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 13-19 and 25-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 19.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Newly submitted claim 28 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the Species elected does not have a tapered portion, and therefore the claim is withdrawn.
2. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 28 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-4, 6, 13-17, 18, and 27 are rejected under 35 U.S.C. 102(e) as being anticipated by Allen et al. (USPN 6,334,856).

Allen et al. discloses a microneedle array comprising a plurality of microneedles with a plurality of projections which extend from the second side of said base element and wherein said projections are spaced by a range of 50-1000 micron (Column 14,

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lines 18-20) and wherein said length of projections are 50-3000 micron (Column 5, lines 39-58). (Figures 1A, 1B, 3G, 4D, and Entire reference)

5. Claims 1, 13, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Gerstel et al. (USPN 3,964,482).

Gerstel et al. discloses the microneedle array comprising a plurality of microneedles with a plurality of projections which extend from the second side of said base element and wherein said projections are spaced by a range of 50-1000 micron (Column 7, lines 42-45) and wherein said length of projections are 50-3000 micron (Column 7, lines 64-65).

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-7, 13-19, and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen et al. as applied above, and further in view of Reed et al. (USPN 5676850).

Allen et al. disclosed the claimed invention except for the hollow element having at least two sharp projections proximal to an end of the hollow element.

Reed et al. disclosed an hollow elements each exhibit an edged outer contour, in a transverse plane, that is perpendicular to a longitudinal axis of said hollow element,

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said outer contour having at least 2 shape projections (Figure 7, 13 and entire reference)

At the time of the invention it would have been obvious for one of ordinary skill in the art to combine the device of Allen et al. with the teachings of Reed et al. because Reed et al. discloses a more efficient way to anchor the infusion structure to the organ body.

Therefore, it would have been obvious to one of ordinary skill in the art to combine Allen et al. with Reed et al. to obtain the invention as specified in claims 1-7, 13-19 and 25-27.

### ***Double Patenting***

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims. Although the conflicting claims are not identical, they are not patentably distinct from each other because they disclose

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10. Claims 1-7, 13-19, and 25-27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 6,652,478 [Gartstein et al.] in view of U.S. Patent No. 6,334,856 [Allen et al.], because Garstein et al. discloses the same microneedle structure that is claimed in this application and Allen et al. discloses the separation and length of the microneedles on a base. It would have been obvious to combine the two reference because it is well known in the medical art when using microneedles to make them a certain length and as well as having a certain separation distance so that the microneedle will perform their function appropriately, which is to be able to inject fluid through the upper layer of the skin without affecting the lower layer of the skin and the nerve ends.

#### ***Response to Arguments***

11. Applicant's arguments filed 12/24/03 have been fully considered but they are not persuasive.

12. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., parallel, the term is substantially parallel which broadens the interpretation and make the claimed invention not have to be parallel) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). This interpretation is also true for substantially longitudinal.

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13. To help expedite this case the examiner suggests stating the projections are on the outer surface (outer contour) of the microneedle, wherein the projections extend at the base of the microneedle to the distal end of the microneedle at the tip along the same longitudinal direction as the microneedle or in a parallel direction with the microneedle and wherein the microneedle is a hollow needle.

### ***Conclusion***

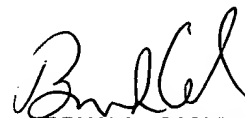
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F DeSanto whose telephone number is 1-703-305-3292. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 1-703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Matthew DeSanto  
Art Unit 3763  
April 17, 2004



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